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No. 93-1251

IN THE

Supreme Court of the United States

OCTOBER TERM, 1993

DONNA E. SHALALA,
Secretary of Health and Human Services,
Petitioner,
vs.
GUERNSEY MEMORIAL HOSPITAL,
Respondent.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

BRIEF *AMICI CURIAE* OF THE AMERICAN HOSPITAL ASSOCIATION, THE FEDERATION OF AMERICAN HEALTH SYSTEMS, THE CALIFORNIA ASSOCIATION OF HOSPITALS AND HEALTH SYSTEMS, AND THE TEXAS HOSPITAL ASSOCIATION IN SUPPORT OF RESPONDENT

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QUESTIONS PRESENTED

1. Whether the Secretary of Health and Human Services' denial of respondent's claim for its reasonable costs incurred according to generally accepted accounting principles or GAAP conflicts with Medicare regulations.

2. Whether, if Medicare regulations do not require GAAP be used to determine Medicare allowable costs, a guideline relied upon by the Secretary to deny reimbursement is invalid under the Medicare Act and the Administrative Procedure Act.

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INTEREST OF *AMICI CURIAE*

With the written consents of both parties, which have been filed with the Court, *amici curiae* respectfully submit this brief in support of respondent Guernsey Memorial Hospital.

Amici curiae are four hospital associations. The American Hospital Association ("AHA"), an Illinois corporation, is the primary organization of hospitals in the United States. AHA represents approximately 5,400 hospitals and other health care institutions. The Federation of American Health Systems, a New York corporation, represents approximately 1,400 investor-owned hospitals and 350 managed hospitals throughout the country. The California Association of Hospitals and Health Systems and the Texas Hospital Association are organized under the laws of their respective states and are the statewide hospital organizations in their states. *Amici's* members include most of the nation's hospitals.

The overwhelming majority of *amici's* institutional members participate as providers of services in the Medicare program. 42 U.S.C. §§ 1395-1395ccc. Payments made to hospitals on behalf of beneficiaries of the Medicare program account for approximately 40% of the revenue of most member hospitals. Reimbursement for services furnished to Medicare beneficiaries is a major factor considered by such hospitals in their financial planning, and can affect the continued ability of hospitals to provide needed services to Medicare beneficiaries and others in the community. Accordingly, *amici* have an immediate and continuing concern regarding the consistent application of the Medicare statute and implementing regulations, as well as the integrity and reliability of the procedures used to implement changes

in the reimbursement rules applicable to Medicare providers.

At issue in this case is an attempt by the Secretary of Health and Human Services ("Secretary") to avoid her own regulations regarding accrual basis accounting and generally accepted accounting principles ("GAAP"), as well as her attempt to bypass the rulemaking requirements of the Administrative Procedure Act, 5 U.S.C. § 551 *et seq.* ("APA"), in her administration of the Medicare program. *Amici* suggest that the Court reject the Secretary's efforts to reinterpret her rules regarding the applicability of GAAP to Medicare cost determinations. Moreover, the Court should reject the Secretary's attempt to issue legislative rules through the Provider Reimbursement Manual ("PRM") without regard to rulemaking procedures. Instead, this Court should adopt the reasoning of the court of appeals below, which properly applied the clear terms of the Secretary's regulations addressing GAAP, and which is consistent with the APA and the critically important policy considerations underlying it.

SUMMARY OF ARGUMENT

As the court of appeals found below, the Secretary seeks to avoid the plain terms of her Medicare regulations which provide that Medicare costs are to be determined in accordance with GAAP. These regulations do not exist simply by reason of the Secretary's general rulemaking authority, but were specifically mandated by the Medicare statute which requires the issuance of regulations to establish the method or methods to be used to determine Medicare costs.

In claiming that the regulations at issue here do not provide for GAAP, neither the final agency decision

below, nor the Secretary's brief here, addresses the terms of her regulations. Read as a whole, the regulations create a direct relationship between provider books and records maintained in accordance with GAAP and the determination of Medicare costs. They specifically link provider records to the cost determination process.

For many years, final agency decisions have interpreted the regulations in question to require the application of GAAP in determining Medicare costs. The Secretary has argued before the courts that GAAP applies pursuant to her regulations, particularly where GAAP would reduce Medicare costs. The Secretary has taken inconsistent positions regarding the application of GAAP under her regulations, however, depending on her litigating strategy.

The Secretary's current interpretation of the regulation is designed to avoid the notice and comment rulemaking requirements of the APA. If the regulations do not establish GAAP as the primary basis for determining Medicare costs, the Secretary asserts that she need not comply with the APA in issuing rules that are inconsistent with GAAP. Because Congress has directed the Secretary to exercise her legislative rulemaking authority through regulations, however, she is not free to establish a method of determining costs through a mere interpretive rule. The rule at issue in this case is a substantive rule that can be adopted only in accordance with the procedural requirements of the APA. Any other result would seriously threaten the integrity of the rulemaking process.

ARGUMENT

I. THE SECRETARY'S MEDICARE REGULATIONS REQUIRE GAAP AND ACCRUAL BASIS ACCOUNTING BE USED IN DETERMINING MEDICARE COSTS UNLESS OTHERWISE PROVIDED BY REGULATION.

A. The Secretary's Construction Of Her Regulations Violates Their Clear Terms.

The Medicare statute, 42 U.S.C. § 1395x(v)(1)(A), requires that the actual reasonable costs incurred by providers for services to beneficiaries "shall be determined in accordance with regulations establishing the method or methods to be used . . . ."[1] Regulations implementing this mandate appear at Title 42 C.F.R., Part

[1] Effective for cost reporting periods beginning on and after October 1, 1983, Medicare directed that most hospitals in the country be paid their operating costs, not on the basis of their reasonable cost, but on the basis of prospectively determined rates. However, the Secretary continued to pay certain costs, including costs defined as capital-related costs, on the basis of reasonable costs actually incurred. Social Security Amendments of 1983, Pub. L. No. 98-21, §§ 601-607, 97 Stat. 149-172 (1983). The costs involved in this case are deemed by the Secretary to be capital-related costs and were paid on a reasonable cost basis. For cost reports beginning on or after October 1, 1991, capital-related costs are also paid on a prospectively determined basis. *See* 42 U.S.C. § 1395ww(g)(1)(A).

Because virtually all costs of hospital inpatient services are now paid under Medicare's prospective payment system, the future significance of the specific regulations at issue in this case is greatly diminished. The issue of whether the Secretary is required to issue regulations with respect to Medicare's payment system remains of extreme importance to *amici* and its members.

413, and are entitled "Principles of Reasonable Cost Reimbursement."

Although amended and supplemented, these principles have been in place since the beginning of the Medicare program. *See* 31 Fed. Reg. 14,808 (Nov. 22, 1966), *codified at* 20 C.F.R. §§ 405.401-405.454 (1968).[2] The reimbursement regulations address the specific treatment of certain kinds of costs such as depreciation, interest, costs associated with bad debts, costs involving transactions between related organizations, and costs of educational facilities. *See* 42 C.F.R. §§ 413.134, 413.154, 413.80, 413.17 and 413.85 (1993), respectively. In addition to the specific cost matters addressed, the regulations have, since the program's beginning, addressed provider financial records and the application of accrual basis accounting for purposes of determining allowable costs. These latter regulations are found at 42 C.F.R. §§ 413.20 and 413.24.

The Secretary claims that these sections by their terms do not require the use of GAAP and accrual basis accounting to determine Medicare costs.[3] Brief for the

[2] These regulations were recodified at 42 C.F.R. § 405.401 *et seq.* in 1977. *See* 42 Fed. Reg. 52,826 (Sept. 30, 1977). In 1986, the regulations were redesignated at 42 C.F.R. Part 413. *See* 51 Fed. Reg. 34,794 (Sept. 30, 1986).

[3] The overwhelming weight of authority, including the court of appeals below and three other federal courts of appeals, have disagreed with the Secretary and found that the regulations at §§ 413.20 and 413.24 mandate the use of GAAP and accrual basis of accounting in determining how Medicare costs are paid. *See, e.g., Mother Frances Hosp. of Tyler, Texas v. Shalala*, 15 F.3d 423 (5th Cir. 1994); *HCA Health Services of Midwest, Inc. v. Bowen*, 869 F.2d 1179, 1181 (9th Cir. 1989); *Charlotte Memorial Hosp. & Med. Center v. Bowen*, 860 F.2d 595, 600 (4th Cir. 1988); *National Medical Enterprises v. Bowen*, 851 F.2d 291 (9th Cir. 1988); *Villa*

(continued)

Petitioner ("Pt. Br.") at 27. Instead, she claims these regulations only impose record-keeping requirements on hospitals. But her argument makes only passing reference to the actual terms of these regulations and ignores their requirements in the context of the regulatory scheme.

As the court of appeals in its decision below noted, the language in 42 C.F.R. § 413.20(a) requiring that hospitals follow standardized accounting practices that are widely accepted in the hospital field, "does not exist in a vacuum." Appendix to Petitioner's Brief ("Pet. App.") at 11a. This requirement exists in the context of the "principles of cost reimbursement" referred to in the prior sentence of the regulation which requires "that providers maintain sufficient financial records and statistical data *for proper determination of costs payable under the program.*" 42 C.F.R. § 413.20(a) (emphasis added). The Secretary interprets this provision to require that financial records be maintained consistently with widely accepted reporting practices, so that under some *other* system-wide method of determining costs, unstated in her regulations, the costs payable under the program will be properly determined. Under the Secretary's construction, there is a vague relationship between hospital financial records and the determination of costs which does not appear in the regulations.

The district court in Maine dismissed the Secretary's argument as requiring two separate accounting systems to be maintained, stating:

(fn. continued)
View Community Hosp., Inc. v. Heckler, 720 F.2d 1086, 1093 n.18 (9th Cir. 1983).

> The [Secretary's] argument is illogical. The Secretary mandates certain record keeping requirements precisely because the provider is entitled to reimbursement of reasonable costs. . . . To suggest that the Secretary required providers to seek reimbursement under one accounting system while he intended to make payment under another is contrary to the structure of the regulations.

Mercy Hospital v. Sullivan, (D. Me. 1991), *reported at* Medicare & Medicaid Guide (CCH) ¶ 40,227 at 30,603 (*quoting St. Luke's Hosp. v. Secretary of Health & Human Serv.*, 632 F. Supp. 1387, 1391 (D. Mass. 1986), *vacated on other grounds*, 810 F.2d 325 (1st Cir. 1987)).

Contrary to the Secretary's position, her regulations provide for a direct relationship between the maintenance of hospital financial records and books of account and the proper determination of costs payable under the program. As noted, the first sentence of § 413.20(a) addresses the principles of cost reimbursement which require that sufficient data be maintained "for proper determination of costs payable under the program." This sentence, standing alone, strongly suggests that the data maintained by the provider is the basis for determining costs. Next, according to the subsection, hospitals must maintain their books and records in accordance with standardized definitions, accounting, statistics and reporting practices that are widely accepted in the hospital and related fields. Generally accepted accounting principles have always provided the standard definitions and accounting practices applied by non-government hospitals in maintaining their books and records. *See, e.g.*, American Institute of Certified Public Accountants, *Audits of Providers of Health Care Services*, § 3.01 (1993) ("Financial statements of health care entities

should be prepared in conformity with generally accepted accounting principles.") No other standardized definitions exist for such hospitals or are widely accepted so far as is known to *amici*.

Immediately following the requirement that standardized definitions, accounting, statistics, etc., be followed is the provision that changes in hospital accounting practices and systems will not be required "in order to determine costs payable under the principles of reimbursement." This sentence does not provide that a hospital's financial records will be adapted in some manner to accommodate the methods to be announced by the Secretary for determining costs. Instead, it reaffirms that costs will be determined from the hospital's financial records without requiring that those records be modified.[4]

The last sentence of § 413.20(a) states that "the methods of determining costs payable under Medicare involve making use of data available from the institution's basic accounts, as usually maintained, to arrive at equitable and proper payment for services to beneficiaries." The only natural reading of the sentence is that the "basic accounts as usually maintained" form the basis for determining costs payable under the program.[5] Otherwise, how are the "basic accounts as usually maintained" involved in the methods of determining costs?[6]

[4] As the court of appeals below stated, the Secretary can, of course, depart from GAAP by validly issued regulations. *See* Pet. App. at 6a.

[5] Section 413.20(d) specifies provider record-keeping requirements in some detail. It requires providers to furnish information to intermediaries regarding several matters including costs of operation. 42 C.F.R. § 413.20(d)(2)(vii). Under the Secretary's construction, the record-keeping requirements of subsection (d) regarding costs of operation are superfluous.

The accrual accounting regulation at § 413.24 is even more specific in its application to the determination of costs to be paid by Medicare. Referring only to subsection (b) of this regulation which defines the accrual basis of accounting, the Secretary concludes that the regulation addresses only the manner in which information must be "reported" in a provider's books, but not how it is to be used in determining costs. *See* Pt. Br. at 24-25. But the regulation is actually much more specific.

Subsection (a) refers to "cost data" which must be provided to the Secretary to support payments to providers for their reimbursable costs. The "cost data" must be based on providers' financial and statistical records which can be verified by audit and must be based on the accrual basis of accounting. *See* 42 C.F.R. § 413.24(a), (b). Subsection (e) of the regulation confirms that the cost data maintained in accordance with the accrual basis of accounting is the basis on which costs are determined. It provides that "[t]he cost data submitted must be based on the accrual basis of accounting *which is recognized as the most accurate basis for determining costs*." (emphasis added). This statement, coupled with the requirement that cost data must be submitted on the accrual basis of accounting in order to support payments to providers, leaves no doubt as to the use of accrual basis accounting in the cost determination

[6] The Secretary answered this question in her brief to the court of appeals for the ninth circuit by representing that "the regulations provide that the *essential methods of determining reimbursable costs* 'involve making use of data available from the institution's basic accounts as usually maintained. . . .' 42 C.F.R. § 405.406(a)." (emphasis added). *See* Brief for Appellee at 4-5 filed in *HCA Health Services of Midwest, Inc. v. Bowen, Secretary of Health and Human Services*, 869 F.2d 1179 (9th Cir. 1989).

process. Not even the Secretary's reinterpretation can avoid the regulation's plain language which provides that accrual basis accounting is the most accurate basis for determining costs rather than merely a record-keeping standard.

The claim that § 413.20 serves only a record-keeping purpose is assertedly supported by reference to its original placement at the end of what the Secretary considers "prefatory sections" of the initial Medicare regulations. Pt. Br. at 26. In fact, the Secretary has made clear that this regulation is part of the reasonable cost reimbursement rules. Prior to 1986, former § 405.406 (now § 413.20) was included with other regulations under a center heading of "Reasonable Cost Reimbursement: General Rules" and former § 405.453 (now § 413.24) was grouped with other regulations under a center heading of "Additional General Rules on Reasonable Cost Reimbursement." *See* 42 C.F.R. Part 413 (1984). The center headings, while not a part of the regulations themselves, demonstrate that the Secretary considered these regulations to be part of the general principles of reimbursement, and that they were intended to do more than "provide general reassurance to providers" that their accounting practices would not have to be changed. Pt. Br. at 26.

Under the center headings, former §§ 405.406 and 405.453 were grouped with regulations which set forth *mandatory* principles of reimbursement. For example, immediately following former § 405.406, and under the same center heading, was former § 405.414 which expressly limited the definition of, and reimbursement for, capital-related costs in a manner which departed from GAAP. *See* 42 C.F.R. § 405.414 (1984). Similarly, the placement of § 405.453 with a group of regulations under the center heading "Additional General Rules on

Reasonable Cost Reimbursement" groups it with other regulations which specify the manner in which costs are to be determined. It was not until the regulations were redesignated from Part 405 to Part 413 in 1986 that the Secretary grouped §§ 413.20 and 413.24 together under a center heading entitled "Accounting Records and Reports." *See* footnote 2, *supra*. Far from supporting the Secretary's claim that these regulations were intended as record-keeping rules only, it is clear from the placement of the regulations until 1986 that they were part of the Secretary's mandatory reimbursement principles which were applied in determining Medicare costs.[7]

As the court of appeals stated below, the Secretary cannot ignore the structure of her regulations in interpreting their terms. *See* Pet. App. at 11a. As this Court noted in a case involving the construction of statutory language, "the court must look to the particular . . . language at issue, as well as the language and design of the statute as a whole." *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 291 (1988).

If §§ 413.20(a) and 413.24 do not impose GAAP as the basic method for determining costs, then no regulation exists which specifies an overall methodology to be applied in the cost determination process. This absence not only violates the clear instructions of Congress contained in 42 U.S.C. § 1395x(v)(1)(A), but leaves a void in the method to be applied by hospitals in determining their Medicare costs. The Secretary claims that this void is filled by the Foreword to the PRM and/or by the

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[7] The district court below, apparently unaware that the Secretary retitled these sections in 1986, concluded that § 413.20 did not deal with cost reimbursement, in part, because it was titled "Financial Data and Reports." *Guernsey Memorial Hosp. v. Sullivan*, 796 F. Supp. 283, 290-91 (S.D. Ohio 1992).

Secretary's Federal Register notice published at 41 Fed. Reg. 46,291, 46,292 (Oct. 20, 1976), each of which direct GAAP be used only when a cost situation is not otherwise addressed. *See* Pt. Br. at 28, 30 n.17. But these notices do not conform to the statute's requirement that regulations issue to establish the methods to be used in determining costs. The Secretary seeks to minimize the importance of GAAP by arguing that it is only a "stop-gap" in the cost determination process because GAAP is only applied for cost situations not otherwise covered by her policies. Pt. Br. at 28. Even if this were true, the use of GAAP as a comprehensive "stop-gap" to Medicare cost determinations would surely be such a fundamental element in the reimbursement system as to constitute one of the methods to be used in cost determinations; as such, it could only be implemented by regulation as required by § 1395x(v)(1)(A).

But far from a "stop-gap," it is clear that hospitals' books and records, as maintained under GAAP, form the *primary* basis on which Medicare costs are determined. In fact, the Secretary's cost reporting forms and instructions require that the cost report be completed from the financial records and basic books of accounts of the provider.[8] The cost report instructions require that the initial schedule of the cost report, entitled "Worksheet A," incorporate the trial balance of expense accounts from the provider's accounting books and records. PRM, Part II, Ch. 28, § 2807, *reprinted in* Medicare & Medicaid Guide (CCH), Report No. 773, dated October

[8] Cost reports are the forms used by providers to claim their Medicare allowable costs. *See* 42 C.F.R. §§ 413.20(b), 413.24(f). Cost reporting forms contain numerous schedules which incorporate most categories of costs directly from a provider's books and records. *See* PRM, Part II, Ch. 28, which sets out the provider cost reporting forms and instructions.

29, 1993. The trial balance of expense accounts is a summary of the various expense ledgers maintained by the provider in accordance with GAAP. Moreover, the provider is required to certify that the cost report "is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted." *See* HCFA Form 2552-92 (9/93), *reprinted in* Medicare & Medicaid Guide (CCH), Report No. 773, dated October 29, 1993.

Rather than specifically addressing the language of her regulations, the Secretary, citing to her "broad authority" to determine the method or methods of reimbursement, asserts that she is not obligated by statute to apply GAAP and accrual accounting as the basis for her cost reimbursement principles, and that GAAP and Medicare have different objectives. Pt. Br. at 19-23. However, there is no inconsistency between these assertions and the conclusion that the regulations require GAAP as the method of determining costs. The Secretary, faced in 1966 with the need to develop a comprehensive system of cost reimbursement principles, wisely adopted one which was already available, widely recognized, in use, and fully comprehensible to providers. While it is possible to conceive of a system to determine costs other than GAAP and accrual basis accounting, none has been suggested by the Secretary.[9] Nor does she refer to any interpretation, whether judicial or administrative, which would reasonably provide an alternative to the use of GAAP as the fundamental basis for determining reasonable costs.

If, as the Secretary asserts, GAAP is not the frame of reference in her regulations for determining allowable

[9] The Secretary could, of course, have mandated cash basis accounting as the basis for determining costs.

costs, then the regulations are silent as to the relationship between financial records and Medicare allowable costs. More importantly, there would be *no regulation* under which costs are uniformly and systematically determined, leaving a "black hole" in the regulations regarding the methods to be used in that determination.

B. The Secretary's Agency Decisions Are Inconsistent With Her Present Construction Of The Regulations.

The Secretary claims that her interpretation of the regulations is supported by consistent and long-standing agency practice and interpretation. Pt. Br. at 28. But this claim is contradicted by the agency's prior actions in applying the same regulations. In numerous final agency decisions, the Secretary concluded that her regulations at §§ 413.20(a) and 413.24 (and their predecessor regulations at 42 C.F.R. §§ 405.406(a) and 405.453 (1984)) specifically provide for the application of GAAP and accrual basis accounting in determining costs. For example, in *Dr. David M. Brotman Memorial Hospital v. Blue Cross Association, et al.*, HCFA Admin. Dec. (1980), Medicare & Medicaid Guide (CCH) ¶ 30,922 at 9839, the Deputy Administrator not only held that § 405.406 requires that GAAP be followed, but applied GAAP in lieu of a PRM provision which treated the particular expense in a manner inconsistent with GAAP. He held that: "Under 42 C.F.R. 405.406, the determination of costs payable under the program should follow standardized accounting practices. . . . In this regard, under generally accepted accounting principles, credit card sales would be recorded individually at the full amount of the sale when the transaction occurred . . ." and concluded that credit card costs should be treated as

an expense rather than a reduction of revenue as required by a Medicare directive to the contrary.

Similarly, in *Biscayne Medical Center v. Blue Cross Association, et al.*, HCFA Admin. Dec. (1982), Medicare & Medicaid Guide (CCH) ¶ 32,304 at 9499, the Deputy Administrator held that the costs in question could not be recognized as reimbursable, stating, "[u]nder 42 C.F.R. 405.453, Medicare cost finding and reimbursement is based on the accrual basis of accounting. Under this method, a potential receivable would not be recorded as such in the provider's financial statements until it is definite and the amount can be reasonably determined. . . . In this case, the Medicare receivable is contingent upon the provider winning [another appeal issue]. Until the final determination . . . the provider cannot reasonably expect to receive any additional reimbursement."

In another final agency decision, *HCA Home Office Stock Option Group Appeal v. Blue Cross and Blue Shield Association, et al.*, PRRB Dec. No. 85-D49 (1985), Medicare & Medicaid Guide (CCH) ¶ 34,630 at 10,123, the Provider Reimbursement Review Board ("Board") upheld the intermediary's decision disallowing costs because it "implemented the requirements of 42 C.F.R. 405.406(a) that costs be defined . . . by following GAAP, as set forth in APB 25 . . . ." The Board further concluded that "42 C.F.R. 405.453(a) and (b) require cost data [be maintained] on the accrual basis of accounting . . . [and] since 42 C.F.R. 405.453(a) requires that the subject cost be accrued, the providers did not fulfill that requirement. . . ."[10]

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[10] To the same effect are: *Broadway Community Hosp. v. Blue Cross Ass'n, et al.*, PRRB Dec. No. 82-D94 (1982), Medicare & Medicaid Guide (CCH) ¶ 32,001 at 9889; *Rapides General Hosp. v.*

(continued)

In litigation, the Secretary has also relied on GAAP to deny reimbursement of costs based on her regulations. *See HCA Health Services of Midwest, Inc. v. Bowen*, 869 F.2d at 1180-81. *See also National Medical Enterprises v. Bowen*, 851 F.2d at 293. Moreover, there has been no consistent agency practice to apply GAAP where Medicare program policies are silent. The Secretary has refused to apply GAAP where there was no Medicare directive to the contrary. For example, in *OrNda HealthCorp v. Shalala*, (E.D. Ark. 1993), *reported at* Medicare & Medicaid Guide (CCH) ¶ 41,975, appeal withdrawn, the Secretary rejected GAAP as the basis to determine the costs associated with a capital lease. Neither the regulations nor the PRM addressed capital lease costs and neither contained a provision for denying such costs. The district court reversed the Secretary's decision and concluded that GAAP and accrual accounting apply to determine the costs of capital leases

(fn. continued)
Blue Cross Ass'n, et al., PRRB Dec. No. 82-D35 (1982), Medicare & Medicaid Guide (CCH) ¶ 31,703 at 10,263; *Greene County General Hosp. v. Blue Cross and Blue Shield Ass'n, et al.*, PRRB Dec. No. 86-D38 (1985), Medicare & Medicaid Guide (CCH) ¶ 35,353 at 10,857; *Woodruff Community Hosp. v. The Travelers Ins. Co.*, PRRB Dec. No. 91-D40 (1991), Medicare & Medicaid Guide (CCH) ¶ 39,208 at 26,285; *Comprehensive Home Health Care, Inc. v. Blue Cross and Blue Shield Ass'n, et al.*, PRRB Dec. No. 91-D21 (1991), Medicare & Medicaid Guide (CCH) ¶ 39,084 at 25,466-67; *Woodland Park Hosp. v. Blue Cross and Blue Shield Ass'n, et al.*, PRRB Dec. No. 91-D30 (1991), Medicare & Medicaid Guide (CCH) ¶ 41,332 at 35,134; *National Medical Enterprises, Inc. Group Appeal*, PRRB Dec. No. 93-D2 (1992), Medicare & Medicaid Guide (CCH) ¶ 40,933 at 33,849-50; *Republic Health Group Appeal - Favorable Leasing v. Blue Cross and Blue Shield Ass'n, et al.*, PRRB Dec. No. 93-D11 (1993), Medicare & Medicaid Guide (CCH) ¶ 41,005 at 34,322.

pursuant to §§ 413.20 and 413.24.[11]

Amici submit it is bad policy, as well as bad law, to permit the Secretary to rely on her regulations to apply GAAP when convenient, and to deny the applicability of those same regulations when it is not. The agency's inconsistent action in applying GAAP to determine costs substantially reduces any deference due the Secretary. *See* discussion in Brief For The Respondent at 20-21.

II. SECTION 233 OF THE PROVIDER REIMBURSEMENT MANUAL IS INVALID FOR FAILURE TO COMPLY WITH THE REQUIREMENTS OF THE MEDICARE ACT AND THE ADMINISTRATIVE PROCEDURE ACT.

A. The Medicare Statute And The APA Require That Substantive Rules Regarding Reimbursement Be Established By Regulation.

The Medicare statute at 42 U.S.C. § 1395x(v)(1)(A) expressly delegates to the Secretary legislative authority to give substantive meaning to the vague statutory concept of "reasonable costs" through regulations. *See Good Samaritan Hosp. v. Shalala*, 113 S. Ct. 2151, 2154 (1993). As noted, the statute directs that regulations issue to establish the method or methods to be used in

[11] The Secretary has also refused to apply GAAP in other cases involving the cost of capital leases, although no Medicare directive addressing such costs exists. *See, e.g., Methodist Hosp. of Lexington, Inc. v. Blue Cross & Blue Shield Ass'n*, HCFA Admin. Dec. (1991), Medicare & Medicaid Guide (CCH), ¶ 39,469, *aff'd, Methodist Hosp. of Lexington, Inc. v. Sullivan*, C.V. No. 91-2684-HB, (W.D. Tenn. 1993) (unreported).

determining costs. If, as the Secretary asserts, her regulations are silent as to a systematic methodology for determining reasonable costs, PRM § 233 (which represents the Secretary's attempt to address one category of costs, those incurred in a bond defeasance) stands alone as a substantive rule which must be issued in accordance with the notice and comment rulemaking requirements of the APA. 5 U.S.C. § 553(b).[12]

There is no dispute that § 233 constitutes a "rule" as that term is defined in the APA. *See* 5 U.S.C. § 551(4). Nor is there any question that if § 233 is a "substantive" or "legislative" rule, it is subject to the requirements of the APA. *See Lincoln v. Vigil*, 113 S. Ct. 2024, 2033 (1993). While the term "substantive rule" is not defined in the APA, the Attorney General's Manual on the Administrative Procedure Act (1947) describes substantive rules as those "issued by an agency pursuant to statutory authority and which implement the statute. . . ." *Id.* at 30 n.3. The Court has characterized such rules as those "affecting individual rights and obligations." *Morton v. Ruiz*, 415 U.S. 199, 232 (1974). Such rules are deemed to "grant rights, impose obligations, or produce other significant effects on private interests." *Rosetti v. Shalala*, 12 F.3d 1216, 1222 n.15 (3rd Cir. 1993), *citing American Ambulance Serv. v. Sullivan*, 911 F.2d 901, 907 (3rd Cir. 1990) (*quoting Batterton v. Marshall*, 648 F.2d 694, 701-02 (D.C. Cir. 1980)).

The Court has recognized that § 1395x(v)(1)(A) does not merely authorize the Secretary to issue regulations but, in fact, "directs" the Secretary to promulgate regulations establishing methods to be used in determining

[12] The Secretary apparently concedes that if Medicare regulations require the application of GAAP in the determination of reasonable costs, § 233 of the PRM is invalid. *See* Pt. Br. at (I).

reasonable costs. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 210 (1988). "Rather than attempt to define 'reasonable cost' with precision, Congress empowered the Secretary to issue appropriate regulations setting forth the methods to be used in computing such costs." *Good Samaritan Hosp. v. Shalala*, 113 S. Ct. at 2154. As the Court noted in *Good Samaritan Hospital*, aside from the agency's determination made pursuant to its regulations, there is no available standard of reasonableness. 113 S. Ct. at 2158. Therefore, in establishing methods for determining reasonable costs, the Secretary is not merely interpreting a statutory term. Instead, such rules implement the statute and grant rights, impose obligations and significantly affect private interests. Applying the definitions discussed above, they are substantive rules subject to the procedural requirements of the APA.

The Court has also recognized that where an express delegation is made by Congress, "[i]n exercising that responsibility, the Secretary adopts regulations with legislative effect." *Batterton v. Francis*, 432 U.S. 416, 425 (1977). The statutory delegation in that case appeared in Title IV of the Social Security Act, granting the Secretary the power to prescribe standards for determining when a father is unemployed for purposes of eligibility for benefits under the Aid to Families with Dependent Children Program. 42 U.S.C. § 607(a). Again in *Schweiker v. Gray Panthers*, 453 U.S. 34, 44 (1981), the Court recognized that the language of the Medicaid statute, 42 U.S.C. § 1396a(a)(17)(B), directing the Secretary to prescribe standards for determining the availability of income and resources, constituted an "explicit delegation of substantive authority" to define the term "available." In exercising her authority to define reasonable costs pursuant to the directive of

§ 1395x(v)(1)(A), the Secretary similarly exercises substantive authority and issues legislative rules.

Although the Secretary asserts that the regulations "already provide ample 'legislative authority' for reimbursement of bond issuance costs" (Pt. Br. at 39), the provisions relied on by the Secretary indicate to the contrary. The reader will search in vain among the regulations cited by the Secretary for any indication whatsoever regarding the methods (other than GAAP) to be applied in determining either the amount of, or the timing of, the bond defeasance costs incurred by a provider.[13]

The Secretary argues further that nothing in the APA or the Social Security Act "requires the agency to adopt every minute and detailed reimbursement policy and guideline as a 'substantive rule' with the force of law." Pt. Br. at 37. If the Court accepts her characterization of the regulations, however, not only has the Secretary issued § 233 (which she describes as a minute detail) without public participation, but GAAP as a basic principle of Medicare reimbursement has been adopted without the benefit of rulemaking.[14]

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[13] Aside from the application of GAAP, none of the cited regulations sets forth a method for determining such costs. Section 413.5(a) distinguishes the cost-based payment system from a fixed-rate system or prior cost system and sets forth basic principles of allocation of costs among payors; Section 413.9 establishes the principle that costs must be related to patient care, but refers the reader to other regulations for the methods of determining the cost on items included; Sections 413.130 and 413.153 establish that bond defeasance costs are among the types of costs allowable under Medicare, but provide no methodology by which the amount of cost recognized as allowable will be determined.

[14] As the Secretary noted in her Brief to this Court filed on March 24, 1994 in *Thomas Jefferson University v. Shalala*, No. 93-120, the Secretary has "an explicit mandate to formulate regulations to define what reimbursement is due under the Medicare Program," *citing* 42 (continued)

Acknowledging that Medicare costs are determined by GAAP absent a contrary rule, the Secretary cites not her legally binding regulations, but introductory language in the Foreword to the PRM and a brief statement in the 1976 Federal Register publication. Pt. Br. at 28, 30 n.17. But this approach is an unprincipled one because the Secretary seeks to impose GAAP without a regulation so that she can depart from GAAP, not through properly adopted regulations, but through mere policy statements and manual provisions. Pt. Br. at 28, 30 n.17.

Moreover, the Secretary attempts to exercise unfettered discretion by virtue of an open-ended rule similar to that adopted by the Park Service in *United States v. Picciotto*, 875 F.2d 345 (D.C. Cir. 1989). In its regulations, the Park Service retained authority to impose "additional reasonable conditions" in issuing park permits for demonstrations and special events. *See* 36 C.F.R. § 796(g)(5)(xiii)(1988). The court concluded that the Park Service could not impose additional uniform restrictions without engaging in APA notice and comment rulemaking, and concluded that the Park Service's open-ended rule was an attempt by the agency to "grant itself a valid exemption to the APA for all future regulations and be free of APA's troublesome rulemaking procedures forever after, simply by announcing its independence in a general rule." *Id.* at 346-47.

Here, the Secretary goes one step further. Not only does she attempt to grant the agency an exemption to the APA, she attempts to establish the exemption through a

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(fn. continued)
U.S.C. §§ 1395hh, 1395x(v)(1)(A). In that case, the Secretary addressed by regulation a "minute detail" of reimbursement involving community support of educational services which is far less significant than either § 233 or the application of GAAP. *See* Brief for Respondent, *Thomas Jefferson University v. Shalala*, at 21.

mere introductory statement in a Manual and a brief statement buried in a preamble accompanying the publication of a regulation. Under the Secretary's view, she need only adopt one basic regulation, such as 42 C.F.R. § 413.9(b), stating that all costs must relate to patient care, and all of the remaining details can be filled in through the PRM, bypassing the APA entirely. Such an approach was clearly not contemplated by Congress and is directly contrary to the APA.

B. Section 233 Is Not An Interpretive Rule.

The Secretary characterizes § 233 as an interpretive rule or policy statement.[15] Interpretative rules are defined in the Attorney General's Manual on the Administrative Procedure Act (1947) as "rules or statements issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers . . . ." Generally, "[a]n interpretative rule simply states what the administrative agency thinks the statute means, and only 'reminds' affected parties of existing duties. On the other hand, if by its action the agency intends to create new law, rights or duties, the rule is properly considered to be a legislative rule." *General Motors Corp. v. Ruckelshaus*, 742 F.2d 1561, 1565 (D.C. Cir. 1984), *cert. denied*, 471 U.S. 1074 (1985) (citations omitted). Like all exceptions to the notice and comment requirement of the APA, the exception for interpretive rules is to be narrowly construed. *See Sentara-Hampton Gen. Hosp. v. Sullivan*, 980 F.2d 749, 759 (D.C. Cir.

[15] Recognizing the prudence of allowing public input in the rulemaking process, the Secretary waived the grants and benefits exception of 5 U.S.C. § 553(a)(2) in 1971. 36 Fed. Reg. 2532 (Feb. 5, 1971).

1992) and cases cited therein. A rule is not interpretive merely because it sets forth the agency's interpretation of a statutory term. "A rule that performs [an] interpretative function is a legislative rule rather than an interpretative rule if the agency has the statutory authority to promulgate a legislative rule and if the agency intends to exercise that power." Kenneth C. Davis, *Administrative Law Treatise* § 6.3 at 235 (3rd Ed. 1994).

In this case, the Secretary cannot "remind" providers of the existing reasonable cost reimbursement methodology since, under the Secretary's construction, the regulations do not provide for such a methodology. Accordingly, § 233 does more than merely advise the public of the agency's construction of its rules; it creates new law regarding Medicare reimbursement for bond defeasance costs.

While various factors are considered in determining whether a rule is interpretive, the courts have looked to agency intent, as well as to the source and nature of the authority exercised, to distinguish between substantive and interpretive rules. Last year, the court in *American Mining Congress v. Mine Safety and Health Administration*, 995 F.2d 1106, 1112 (D.C. Cir. 1993), adopted a test which looks to the agency's intent to exercise delegated power in order to make such a distinction. The court stated that if any of the following four questions is answered in the affirmative, the rule is legislative, not interpretive: (1) whether in the absence of the rule there would not be an adequate legislative basis for enforcement action or other agency action to confer benefits or insure the performance of duties, (2) whether the agency has published the rule in the Code of Federal Regulations, (3) whether the agency has explicitly invoked its general legislative authority, or (4) whether the rule effectively amends a prior legislative rule. In this case,

the first and fourth tests must be answered in the affirmative.[16]

Applying the first test, there is no legislative basis in the regulations for § 233. Congress expressly left to the Secretary the responsibility for developing a payment methodology by regulation, since the term "reasonable costs" provided an inadequate basis for determining provider reimbursement. *See Good Samaritan Hosp. v. Shalala*, 113 S. Ct. at 2154. The Medicare regulation the Secretary purports to interpret by § 233 is 42 C.F.R. § 413.9. This regulation is simply a broad statement of the principles of reasonable cost reimbursement which provides no substantive guidance in determining when costs are to be recognized. In fact, the very regulation on which the Secretary relies states that reasonable costs "must be determined in accordance with *regulations* establishing the method or methods to be used, and the items to be included." 42 C.F.R. § 413.9(b)(1) (1993) (emphasis added). The only regulations establishing the basic method for determining bond defeasance costs, and most other costs, are now disavowed by the Secretary. Therefore, in the absence of § 233, there would be no basis for the Secretary's denial of costs in this case.[17]

The fourth test of *American Mining Congress* is also met, since the Secretary has consistently applied GAAP as the underlying substantive methodology for determining Medicare reimbursement. As discussed in Section I above, GAAP has been the primary basis for determining

[16] In fact, the third factor is also arguably met here, since the Secretary has cited 42 U.S.C. § 1395x(v)(1)(A) in support of § 233. Pt. Br. at 39.

[17] In this regard, § 233 is similar to the many substantive rules the Secretary attempted to adopt without compliance with the APA which have been invalidated by the courts. *See* footnote 19, *infra*.

Medicare costs. Thus, whatever the source of authority to apply GAAP, it has been the only system-wide method applied by the Secretary. Section 233, requiring a determination in direct conflict with GAAP, effectively amends that prior legislative rule.

The court of appeals for the ninth circuit has adopted a similar analysis looking to "the source of the rule" in determining whether a rule can properly be characterized as interpretive. In *W.C. v. Bowen*, 807 F.2d 1502, 1504 (9th Cir. 1987), the court stated, "[i]f it is promulgated pursuant to statutory directive or under statutory authority, it is a substantive rule." (citation omitted). In *W.C. v. Bowen*, the Secretary was acting pursuant to a congressional directive to implement a program of reviewing decisions rendered by administrative law judges. There, as here, "[i]n exercising that discretion, the Secretary enacted a substantive rule." *Id.* at 1505.[18] *See also Mt. Diablo Hosp. Dist. v. Bowen*, 860 F.2d 951 (9th Cir. 1988) (rejecting the Secretary's purportedly interpretive rule regarding the timing of certain Medicare bonus payments).

Similarly, the sixth circuit in *State of Ohio Department of Human Services v. United States Department of Health and Human Services*, 862 F.2d 1228, 1234 (6th Cir. 1988) found no existing regulatory authority for an eligibility ceiling the Secretary attempted to impose on the Ohio Medicaid program. The court concluded that the ceiling was in no way compelled by the regulation or the underlying statute at 42 U.S.C. § 1396a(a)(17). *Id.*

[18] Where, as in this case, Congress directly commands an agency to issue regulations, such a duty "would not be satisfied with issuance of an humble interpretative rule." *Community Nutrition Inst. v. Young*, 818 F.2d 943, 953 (D.C. Cir. 1987) (Starr, J. concurring in part and dissenting in part).

Because the court concluded that the ceiling was not implicit in the regulation from the beginning, it could not be imposed later without compliance with the notice and comment requirements of the APA. *Id.* at 1236.

In this case, there is nothing explicit or implicit in the existing regulations on which to conclude that the method for determining bond defeasance costs imposed by § 233 would be applied. On the contrary, as discussed in Section I above, the regulations lead to the opposite conclusion. Where a rule results in a change in existing law or policy it is substantive in nature and, as a result, must be promulgated in accordance with the rulemaking requirements of the APA. *Nat'l Family Planning & Reproductive Health Ass'n, Inc. v. Sullivan*, 979 F.2d 227, 240 (D.C. Cir. 1992); *Linoz v. Heckler*, 800 F.2d 871 (9th Cir. 1986).

Moreover, the Secretary's decision to adopt a methodology contrary to GAAP through a mere interpretive rule or policy statement is inconsistent with her prior actions. The Medicare reasonable cost regulations reflect numerous instances in which the Secretary defined costs in a manner contrary to GAAP only after compliance with the APA rulemaking requirements. For example, 42 C.F.R. § 413.134, which addresses depreciation costs, is contrary to GAAP in that it modifies the determination of historical costs, limits the methodology for prorating costs over the useful life of an asset, and provides for the recapture of depreciation by the program upon a gain on the sale of an asset. *See also* 42 C.F.R. § 413.153(b)(2)(iii) (providing for an investment income offset to interest expense); 42 C.F.R. § 413.17 (providing for the recognition of costs relating to items or services obtained from related organizations); 42 C.F.R. § 413.134(h) (special treatment for sale and leaseback transactions).

The regulation adopted in the 1976 Federal Register publication cited by the Secretary here is another example of the Secretary's deviation from GAAP only after compliance with the APA. Following the APA's notice and comment rulemaking procedures, the agency adopted an approach to limit the amount of goodwill to be included in a provider's equity capital which was inconsistent with GAAP. 41 Fed. Reg. 46,291 (Oct. 20, 1976). Moreover, the Secretary continues to adopt rules contrary to GAAP through the APA rulemaking process. *See, e.g.*, 56 Fed. Reg. 50,834 (Oct. 9, 1991) (proposed rule modifying accrual basis accounting). In fact, according to the Secretary's regulatory agenda, she intends to issue a regulation regarding the application of GAAP to Medicare reimbursement determinations generally, presumably to adopt her litigating position in this case. 59 Fed. Reg. 20,312, 20,388 (Apr. 25, 1994).

C. Failure to Comply With APA Procedural Requirements Is Inconsistent With The Intent of Congress.

The APA rulemaking requirements which the Secretary seeks to avoid in this case, were designed to ensure fairness and mature consideration of rules of general application. *NLRB v. Wyman-Gordon Co.*, 394 U.S. 759, 764 (1960), *citing* H.R. Rep. No. 1980, 79th Cong., 2d Sess. 21-26 (1946); S. Rep. No. 752, 79th Cong., 1st Sess. 13-16 (1945). The procedures serve the dual functions of allowing the agency to benefit from the expertise and input of parties who file comments to the proposed rules and to see that the agency maintains a flexible and open minded attitude towards its own rules. *McLouth Steel Prod. Corp. v. Thomas*, 838 F.2d 1317, 1325 (D.C. Cir. 1988).

The Health Care Financing Administration has been among the federal agencies criticized for its frequent nonobservance of the APA in administering the Medicare and Medicaid programs.[19] Robert A. Anthony, *Interpretive Rules, Policy Statements, Guidance, Manuals, And The Like — Should Federal Agencies Use Them To Bind The Public?* 41 Duke L.J. 1311, 1316 n.15 (1992). Congress was also concerned that "important [Medicare] policies are being developed without benefit of the public notice and comment period and, with growing frequency, are being transmitted, if at all, through manual instructions and other informal means." H. Rep. No. 100-391(I), 100th Cong., 1st Sess. § 4073 (1987), *reprinted in* U.S.C.C.A.N. at 2313-250. Accordingly, in 1987, Congress adopted 42 U.S.C. § 1395hh(a)(2), which mandates that "[n]o rule, requirement, or other statement of policy . . . that establishes or changes a substantive legal standard governing . . . payment for services . . . shall take effect unless it is promulgated by the Secretary by regulation." Section 233, which clearly changes a substantive legal standard regarding payment, is precisely the type of rule that concerned Congress when it amended § 1395hh.

The Secretary's extra-record comment indicating that she attempted to comply with the spirit of the APA by

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[19] Numerous attempts by the agency to impose substantive rules through manuals and policy statements have been invalidated by the courts. *See, e.g., Mother Frances Hosp. of Tyler, Texas v. Shalala*, 15 F.3d 423 (5th Cir. 1994); *National Family Planning & Reproductive Health Ass'n, Inc. v. Sullivan*, 979 F.2d 227 (D.C. Cir. 1992); *State of Ohio Dep't of Human Serv. v. U.S. Dep't of Health & Human Serv.*, 862 F.2d 1228 (6th Cir. 1988); *Mt. Diablo Hosp. Dist. v. Bowen*, 860 F.2d 951 (9th Cir. 1988); *W.C. v. Bowen*, 807 F.2d 1502 (9th Cir. 1987); *Samaritan Health Serv. v. Bowen*, 811 F.2d 1524 (D.C. Cir. 1987); *Linoz v. Heckler*, 800 F.2d 871 (9th Cir. 1986).

discussing § 233 with a select group of interested parties illustrates the problems that result from failure to comply with the APA. Pt. Br. at 36 n.21. Such an informal procedure fails to assure the public participation required under the APA. Moreover, the Secretary's approach denies the public, as well as the courts, an adequate explanation of the basis and purpose of the rule. As a result of the Secretary's informal approach in this case, the Court is denied a complete and contemporaneous explanation of why the rule was promulgated. Such an explanation is essential to the Court's review of a rule in the face of a substantive challenge. *See Natural Resources Defense Council v. U.S. Envtl. Protection Agency*, 824 F.2d 1258, 1286 (1st Cir. 1987). Moreover, absent a rulemaking record, the Court cannot determine whether the agency fully considered those comments it received. "An agency decision may not be reasoned if the agency ignores vital comments regarding relevant factors, rather than providing an adequate rebuttal." *Abington Memorial Hosp. v. Heckler*, 576 F. Supp. 1081, 1085 (E.D. Pa. 1983), *aff'd, Abington Memorial Hosp. v. Heckler*, 750 F.2d 242 (3d Cir. 1984), *cert. denied, sub nom. Heckler v. Abington Memorial Hosp.*, 474 U.S. 863 (1985) (citation omitted). Here, the Court's only source of information regarding the "rulemaking process" is a self-serving memorandum prepared by the agency after the hearing at the Board and without opportunity for rebuttal. Joint Appendix at 6-8. Thus, the Secretary's informal process, far from meeting the intent of the notice and comment rulemaking requirements of the APA, actually flies in the face of that provision.

That Congress intended that the Secretary would exercise her delegated, substantive rulemaking authority in accordance with established rulemaking procedures is clear. First, the plain language of the statute mandates the issuance of regulations establishing the method or

methods to be used. 42 U.S.C. § 1395x(v)(1)(A). Moreover, in enacting this section, Congress recognized that it was providing only the broad framework for Medicare reimbursement determinations based on "reasonable costs," and directed that the methods to be used in determining reasonable costs "shall be developed in regulations of the Secretary. . . ." S. Rep. No. 404, 89th Cong., 1st Sess. *reprinted in* U.S.C.C.A.N. at 1976 (1965). Noting that issues relating to payment for hospital services had been "the subject of extended and painstaking consideration for more than a decade," Congress directed the Secretary to take "full advantage" of the experience of private agencies, organizations and associations in developing the regulations. *Id.* The Senate Report specifically noted, "[t]he concept of reasonable cost and the principles and methods for translating this concept into practice in individual circumstances are of concern to consumers, providers of services, insuring organizations, and State and Federal Governmental programs." *Id.* at 1977.

Rather than respond to the congressional directive to make use of the experience of private agencies and organizations, the Secretary seeks to avoid the opportunity to obtain public comment on her rules. Such an approach is not only inconsistent with the directive found in the Medicare statute, but it is inconsistent with the purpose and underlying philosophy of the APA.

CONCLUSION

The Judgment of the United States Court of Appeals for the Sixth Circuit should be affirmed.

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